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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,591	11/18/2003	Janos Pato	AXM-012.3 US	4727

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,591	PATO ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8February2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 16-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 31 May 2007, is acknowledged. Applicants elect, with traverse, Invention II, claims 13-15, classified in class 424, subclass 248.1.

Applicants also elect species 237, i.e., 2-(cyclopropanecarbonyl-amino)-4,5,6,7-tetrahydro-benzo[b]thiophene-3-carbosylic acid amide.

Applicant's election with traverse is on the grounds that all of the claims are generic because noe of the claim are limited to the use of one particular ocmpound or exclude the elected species. This is not found persuasive because of the reasons put forth in the original Restriction Reguirement, i.e., that Invention II is drawn to products which can be utilized in a materially different process from Invention I and III and is a distinct product from that of Invention IV. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 13-15, drawn to compound 237, i.e., 2-(cyclopropanecarbonyl-amino)-4,5,6,7-tetrahydro-benzo[b]thiophene-3-carbosylic acid amide are under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Page 2, line 5, contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 4, line 15, "prtotein" should be "protein"; line 21, "recognising" should be "recognizing"; line 25, "thereapeutics" should be "therapeutics".

Page 13, line 1, "Preferred" should be "preferred".

Page 33, line 26, "mycobateria" should be "mycobacteria".

Page 34, line 20, "kansii" should be "kansasii".

Page 35, line 16, what is meant by "intracutan"?; line 28, "dispersable" should be "dispersible".

Page 45, line 10, "solubilised" should be "solubilized".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are drawn to a "pharmaceutical" composition.

M.P.E.P. §2164.01(c), paragraph 3, recites:

> When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See in re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

Steadman's Medical Dictionary (26th Edition, 1995) defines "pharmaceutical" as "relating to pharmacy or to pharmaceutics"; "pharmacy" as "the practice of preparing and dispensing drugs", and "drug" as "Therapeutic agent; any substance, other than food, used in the prevention, diagnosis, alleviation, treatment, or cure of disease"

While the definition of "pharmaceutical" is broad, it is not so broad to cover any use of a substance on or in the body of a subject, only those uses intended to prevent, diagnose, alleviate, treat, or cure a disease within the animal to which the substance was administered.

In the instant application, the instant specification does not teach how to use the composition, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure of a mycobacterial disease in a host to which the substance is administered.

7. Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibitors of *M. tuberculosis*, *M. smegmatis*, and *M. bovis* serine/threonine kinases, does not reasonably provide enablement for the extremely broad scope of inhibitors of any/all serine/threonine kinases of any/all other species of mycobacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – inhibitors of all serine/threonine kinases in all mycobacterial species.

The state of the prior art as indicated by applicants' references in the instant specification and the reference Peirs et al (Eur. J. Biochem., Vol. 244, pp. 604-612, 1997) indicate that there are as many as 11 eukaryotic-like serine/threonine kinases in *M. tuberculosis* H37Rv alone, and similar genes have been found in *M. bovis*. However, neither applicants' specification nor the art indicate that every species of mycobacteria contains the same serine/threonine kinases or that the inhibitors of one species kinases directly correlates to inhibition of kinases in other species. Therefore, there is a lack of predictability in the art that testing a very limited number of kinases correlates universally to the entire genus of mycobacteria.

The amount of direction/guidance/examples present in the instant specification is insufficient support for the extremely broad scope of the instant claims. The only bacteria utilized in the specification screening process were *M. tuberculosis* H37Rv, *E. coli*, *M. bovis*, and *M. smegmatis*. The only compounds which showed inhibition are listed in Table I (eleven compounds), Table 2 (14 compounds).

Thus, even with relative skill of those in the art for testing compounds, the extremely broad scope of the claims is insufficiently supported by the relatively few compounds which show any inhibitor activity and the use of only three species of mycobacteria.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

August 17, 2007